CPI® PHYSICIAN'S MANUAL

SWEET TIP® Rx

MODELS 4143/4144/4145
AND 4243/4244/4245

STEROID-ELUTING
POSITIVE-FIXATION
POROUS TIP
PACING LEADS

RESTRICTED DEVICE: Federal law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician.

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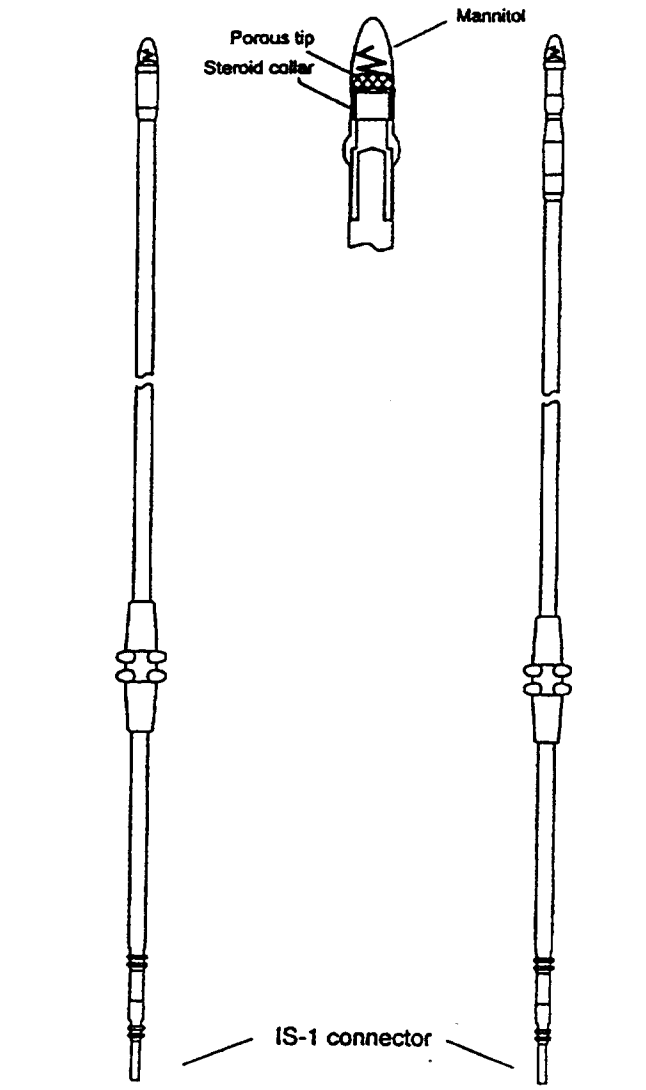
SWEET TIP Rx Leads



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DEVICE DESCRIPTION

Guidant/CPI SWEET TIP® Rx steroid-eluting, porous tip, positive fixation leads, unipolar Models 4143/4144/4145 and bipolar Models 4243/4244/4245, are IS-1* screw-in leads designed for permanent implantation for either atrial and/or ventricular pacing applications.

Instructions in this manual should be used in conjunction with other resource material, including the applicable pulse generator's physician's manual.

INDICATIONS

SWEET TIP Rx steroid-eluting, porous tip, positive fixation leads, unipolar Models 4143/4144/4145 and bipolar Models 4243/4244/4245, are intended for chronic pacing and sensing of the atrium and/or ventricle when used with a compatible pulse generator.

CONTRAINDICATIONS

Do not use this lead in patients with:

- a hypersensitivity to a single dose of 1.0 mg of dexamethasone acetate.
- an allergy to mannitol.
- tricuspid valvular disease.
- mechanical tricuspid heart valves.

WARNINGS AND PRECAUTIONS

Warnings

In the following list of warnings and precautions, page numbers are indicated for those precautions that are specific to other areas of the manual. Refer to the indicated pages for information relevant to the warnings and precaution.

- The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that may be caused by alternating currents.
- Only use properly grounded line-powered equipment in the vicinity of the patient.
- Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.

* IS-1 refers to the international standard ISO 5841.3:1992.

Preprocedure Precautions

- Do not reuse the SWEET TIP Rx lead. The SWEET TIP Rx leads and accessories are intended for one-time use only.
- Do not use unipolar leads having 3.2-mm connectors with pulse generators programmed to the bipolar mode. No output will result.
- Prior to the implantation of this lead, confirm lead/pulse generator compatibility with Guidant/CPI technical services.
- It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse events, refer to the drug manufacturers' labeling.
- Defibrillating equipment should be kept nearby for immediate use during the implantation procedure.
- Lead fracture, dislodgment, abrasion and/or an incomplete connection can cause a periodic or continual loss of pacing and/or sensing.

Lead Handling Precautions

- The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure. Be sure that the vein pick does not puncture the silicone rubber insulation of the lead. This might allow body fluids to seep into the lead and could prevent proper lead function. (Page 13)
- Do not wet the mannitol capsule at the tip of the lead before implantation. This will cause the capsule to begin to dissolve and will shorten the time during which the helix is protected. This may also begin elution of the steroid and may reduce the amount of steroid available when the lead is implanted. (Page 13)
- Always protect the lead conductor insulation from surface contamination (Page 13)
- Do not allow the electrode surfaces to come in contact with surface contaminants. (Page 13)
- To prevent damage to the lead or potential lead dislodgment, do not use excessive force or surgical instruments in handling. Use a suture sleeve to avoid placing the lead under extreme tension. (Page 14)
- Avoid bending the coil conductor; this may weaken the structure. Although pliable, a lead is designed to tolerate only normal flexing and tension. (Page 14)
- Do not apply pressure to the protective capsule over the electrode tip. If the capsule is damaged, the dissolving time may

be shortened and/or the helix may be bent. If the helix is bent, the torsional fracture resistance of the helix may be reduced. (Page 14)

- Do not alter the electrodes or use a lead with a deformed helix. Do not attempt to straighten or realign the fixation helix. (Page 14)
- Mineral oil should never come in contact with a Guidant/CPI porous-tipped lead electrode. Mineral oil on the porous tip may inhibit tissue ingrowth and conduction. (Page 14)

Lead Implantation Precautions

- Do not bend the lead with the stylet in place. Bending the lead may damage the conductor and insulation material. (Page 14)
- When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle to avoid clavicle/first rib damage to the lead. Lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament. Excessive lead compression has also been reported in patients with anatomical abnormalities between the clavicle and first rib. (Page 15)
- When implanting the lead via a subclavian puncture, allow slack in the lead between the distal suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region. (Page 17)
- The method used to direct positive fixation leads through the veins to the heart is different from that used with other leads. To prevent entanglement, use the stylet to steer while rotating the lead body continuously counterclockwise. Use of the lead body for steering may result in tissue snagging and damaging the fixation helix. (Page 17)
- Continuous *counterclockwise* rotation of the lead during maneuvering is necessary to avoid inadvertent tissue trauma. (Page 17)
- Do not rotate the lead *clockwise* until correct position has been achieved and fixation is intended. (Page 18)
- Should dislodgment occur, immediate medical care is required to resolve the electrode position. (Page 18)

- If the stylet begins to turn while fixating the lead, hold the stylet stationary while rotating the lead. Rotating the stylet during electrode fixation dislodges the electrode helix. (Page 19)
- Do not rotate the lead clockwise more than 10 turns when affixing the electrode helix to the heart wall. Excessive rotation may cause helix breakage. (Page 19)
- Do not alter the electrodes or use a lead with a deformed helix. Do not attempt to straighten or realign the fixation helix. (Page 20)
- Chronic repositioning may adversely affect the lead's low-threshold performance because the steroid may be depleted. (Page 20)

Securing the Lead

- Do not kink, twist, or braid the lead terminal with other leads as doing so could cause lead insulation abrasion damage. (Page 22)
- When ligating the vein, avoid too tight a stricture. A tight stricture might damage the silicone rubber insulation or sever the vein. Avoid dislodging the electrode tip during the anchoring procedure. (Page 22)
- Do not remove or cut the suture sleeve from the lead as it may cause lead damage. (Page 22)

Connection to a Pulse Generator

- Remove the stylet and the stylet guide before connecting the lead to the pulse generator. Under no circumstances should the stylet be left in the lead. Leaving the stylet in the lead could cause (1) lead perforation, (2) myocardial perforation, or (3) inability to remove the stylet and reposition the lead. (Page 22)
- Insert the IS-1 lead terminal straight into the lead port. Do not bend the lead. Improper insertion can cause insulation damage near the terminal ring that could result in intermittent sensing. (Page 22)

ADVERSE EVENTS

Observed Adverse Events

Table 1 and Table 2 report complications and observations for the SWEET TIP Rx lead.

Table 1. SWEET TIP Rx Complications and Observations in the Atrium

	# of pts (n=67)	% of pts (95% CI)	# of leads (n=67)	Adverse Events per Lead-Year
Complications[1] (total)	2	3.0% [0.5, 10.5]	2	0.071
Brady capture—none or loss of capture	1	1.5% [0.1, 0.81]	1	0.036
Dislodgment	1	1.5% [0.1, 0.81]	1	0.036
Observations[2] (total)	4	6.0% [1.9, 14.7]	4	0.142
Oversensing	1	1.5% [0.1, 0.81]	1	0.036
Placement difficulty	1	1.5% [0.1, 0.81]	1	0.036
Threshold difficulty	2	3.0% [0.5, 10.5]	2	0.071

Table 2. SWEET TIP Rx Complications and Observations in the Ventricle

	# of pts (n=67)	% of pts (95% CI)	# of leads (n=67)	Adverse Events per Lead-Year
Complications[1] (total)	3	4.5% [1.2, 12.7]	3	0.107
Impedance related, pacing lead, less than 200 ohms	1	1.5% [0.1, 8.1]	1	0.036
Pericardial effusion (chest pain)	2	3.0% [0.5, 10.5]	2	0.071
Observations[2] (total)	6*	9.0% [3.7, 18.6]	7	0.249
Intermittent loss of capture	1	1.5% [0.1, 8.1]	1	0.036
Mesh, fracture or tear suspected	1	1.5% [0.1, 8.1]	1	0.036
Placement difficulty	4*	6.0% [1.9, 14.7]	5	0.178

1. Complications are defined as adverse events requiring invasive measures to correct (eg, surgical intervention).
2. Observations are defined as adverse events which are correctable by noninvasive measures (eg, reprogramming).

* Patients and leads may have multiple AEs.

Potential Adverse Events

Based on the literature and lead implant experience, the possible physical effects from implantation of a SWEET TIP Rx lead are listed below in alphabetical order:

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac perforation
- Chronic nerve damage
- Displacement/dislodgment
- Erosion/extrusion
- Fibrotic tissue formation
- Hematoma
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Keloid formation
- Lead abrasion
- Lead fracture, insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Low amplitude VF signals
- Myocardial injury
- Myocardial irritability
- Pneumothorax
- Post-shock rhythm disturbances
- Random component failures
- Shunting or insulation of current during defibrillation with internal or external paddles
- Transvenous lead-related thrombosis
- Threshold elevation
- Venous occlusion
- Venous perforation

Clinical Studies

Objective:

The objective of this investigation was to validate that the acute stimulation threshold rise of the SWEET TIP Rx lead was less than that of the control lead.

Methods:

Patients were implanted with the SWEET TIP Rx lead or a commercially available, non-steroid control lead in both the atrium and ventricle. The study was randomized 1:1, SWEET TIP Rx to control lead.

Patient Population:

One hundred thirty patients were implanted in the SWEET TIP Rx investigation. A mean implant duration of the entire population was 5.4 months with a cumulative implant

duration of 675 months for the SWEET TIP Rx lead. No statistical differences were found in the baseline variables between the patient groups with respect to demographic profiles. Additional demographic information is presented in Table 3.

Table 3. Description of the Study Population (n = 130 Patients)

Demographics	SWEET TIP Rx	Control
Number of Patients	63	67
Gender		
Male	34 (54.0%)	35 (52.2%)
Female	29 (46.0%)	32 (47.8%)
Age at Implant (years)		
Range	27.9–85.7	43.0–91.0
Mean ± Standard Deviation	69.5±12.5	72.3±11.4

The predominant pacing indications for the study population were third degree heart block 32%, sinus bradycardia (atrial) 23%, brady-tachy syndrome 16%, and sinus arrest/block 11%.

Results

Effectiveness of the SWEET TIP Rx lead was demonstrated by comparing the acute pacing thresholds for the SWEET TIP Rx lead to the commercially-available, non-steroid control lead. Results found in Table 4 and Table 5 demonstrate that the SWEET TIP Rx lead was effective in reducing the typical post-implant threshold rise normally associated with non-steroid leads.

Table 4. Mean Atrial Voltage Threshold (V) at 0.5 ms by Follow-up Period (n = 130)

Follow-up	SWEET TIP Rx		Control		
	Mean (SD)	n	Mean (SD)	n	p-value
Post Implant	0.72 (0.27)	48	0.77 (0.53)	53	0.40
2 weeks	0.80 (0.46)	47	1.25 (0.59)	57	<0.01*
6 weeks	0.76 (0.36)	52	1.48 (1.14)	54	<0.01*
3 months	0.74 (0.35)	44	1.29 (0.82)	51	<0.01*

* Statistically significantly different ($p \leq 0.05$).

Table 5. Mean Ventricular Voltage Threshold (V) at 0.5 ms by Follow-up Period (n=130)

Follow-up	SWEET TIP Rx		Control		
	Mean (SD)	n	Mean (SD)	n	p-value
Post Implant	0.56 (0.18)	44	0.59 (0.24)	54	0.47
2 weeks	0.70 (0.28)	53	1.69 (0.86)	63	<0.01*
6 weeks	0.77 (0.28)	59	1.68 (0.74)	61	<0.01*
3 months	0.76 (0.30)	49	1.52 (0.52)	54	<0.01*

* Statistically significantly different ($p \leq 0.05$).

In the atrium, for a pulse width of 0.5 ms, mean voltage thresholds for the SWEET TIP Rx lead were 35% lower at 2 weeks post implant, 49% lower at 6 weeks post implant, and 43% lower at 3 months post implant compared to the control lead. In the ventricle, for a pulse width of 0.5 ms, mean voltage thresholds for the SWEET TIP Rx lead were 59% lower at 2 weeks post implant, 54% lower at 6 weeks post implant, and 50% lower at 3 months post implant compared to the control lead. Overall, the study data demonstrated a consistent pattern across all voltage and pulse width settings of reduced acute threshold requirements to achieve pacing capture with the SWEET TIP Rx lead.

SWEET TIP Rx lead impedance values in both chambers were obtained using a Pacing System Analyzer (PSA) at time of implant and telemetered pacing diagnostics for subsequent follow-up. Lead impedance was measured at the VIGOR pacemaker settings of 5.5 V, 1.9 ms, and 100 ppm at each follow-up period.

The mean SWEET TIP Rx lead impedance remained above the nominal industry standard of 500 ohms both acutely and after lead maturation.

SWEET TIP Rx P- and R-wave amplitude measurements were obtained using telemetered pacemaker diagnostics during follow-up. The P- and R-wave amplitude measurements were used to demonstrate appropriate electrical compatibility of the SWEET TIP Rx Lead with the pulse generator compared to the control lead. At each follow-up, the amplitude measured for the SWEET TIP Rx was equivalent to the measurements obtained with the Control lead as verified by equivalence test (Blackwelder, 1982) (Table 6 and Table 7).

Table 6. Mean P-wave Amplitudes by Follow-up Period (n=130)

Follow-up	SWEET TIP Rx			Control			Test for Equivalent	
P-wave	Mean (mV)	Std. Dev.	n	Mean (mV)	Std. Dev.	n	t-statistic	p-value
Post Implant	2.63	1.33	57	2.66	1.27	63	-1.97	0.03*
2 weeks	3.15	1.54	50	2.69	1.68	61	-3.85	<0.01*
6 weeks	3.25	1.73	52	2.78	1.55	57	-3.99	<0.01*
3 months	2.94	1.47	50	2.59	1.42	54	-2.97	<0.01*

* Statistically significance $p \leq 0.05$, t-test for equivalent, minimum clinical difference, Δ=0.5 mV.

Table 7. Mean R-wave Amplitudes by Follow-up Period (n=130)

Follow-up	SWEET TIP Rx			Control			Test for Equivalent	
P-wave	Mean (mV)	Std. Dev.	n	Mean (mV)	Std. Dev.	n	t-statistic	p-value
Post implant	8.03	2.50	56	7.89	2.99	60	-3.98	<0.01*
2 weeks	8.36	1.96	50	8.28	2.33	56	-4.03	<0.01*
6 weeks	8.52	2.02	53	7.94	2.74	54	-4.94	<0.01*
3 months	8.17	2.19	50	8.13	2.51	52	-3.56	<0.01*

* Statistically significance $p \leq 0.05$, t-test for equivalent, minimum clinical difference, Δ=1.6 mV.

During the course of the clinical study, there were no deaths confirmed to be SWEET TIP Rx related. There was one complication in the atrium due to a dislodgment. There were two complications in the ventricle both cases of pericardial effusion (chest pain).

Detailed Device Description

The SWEET TIP Rx steroid-eluting, positive fixation, endocardial leads, unipolar Models 4143/4144/4145 and bipolar Models 4243/4244/4245, are atrial and ventricular transvenous pace/sense leads designed for use as an integral part of a pulse generator system with IS-1 ports. The lead uses a platinum-iridium porous-tip electrode with a fixation helix that provides a pacing and sensing surface by promoting fibrotic tissue ingrowth and physically stabilizing the tissue interface. The electrically active platinum-iridium helix anchors the pace/sense electrode to the endocardial surface without support of trabecular structures.

The tip electrode contains a nominal dose of 1.0 mg dexamethasone acetate contained in a silicone rubber collar.

The dissolvable mannitol capsule is designed to facilitate passage of the helix through the heart and blood vessels and to protect the helix from damage. When the electrode tip is inserted into the vein, dissolution begins. The lead body consists of a corrosion-resistant multistrand conductor coil that provides a conductive pathway. The conductor is sheathed in a thin-walled tube of silicone rubber insulation, and is biocompatible and chemically stable for permanent implantation. The IS-1 connector provides a pulse generator connection.

Specific features of SWEET TIP Rx leads include the following:

- **Steroid Distal Electrode:** The tip electrode provides a nominal dose of 1.0 mg dexamethasone acetate contained in a silicone rubber collar. Upon exposure to body fluids, the steroid elutes from the electrode.
- **Low Pacing Thresholds:** The lower threshold performance of this lead permits reduced amplitude and pulse width settings in programmable pulse generators.
- **Fixation Helix:** The electrically active platinum-iridium helix anchors the distal electrode tip to the endocardial surface without support of trabecular structures.
- **Protective Mannitol Capsule:** The dissolvable mannitol capsule is designed to facilitate passage of the helix through the heart and blood vessels and to protect the helix from damage. When the electrode tip is inserted into the vein, dissolution begins. The capsule is completely dissolved within approximately five minutes, enabling the fixation helix to be rotated into the endocardium.
- **Porous Distal Electrode:** The platinum-iridium porous-tipped electrode provides a pacing and sensing surface by promoting fibrotic tissue ingrowth and physically stabilizing the tissue interface.
- **Thin Lead Body:** The lead body consists of a corrosion resistant multistrand conductor coil that provides a conductive pathway. The conductor is sheathed in a thin-walled tube of silicone rubber insulation, and is biocompatible and chemically stable for permanent implantation.
- **IS-1 Connector:** The IS-1 connector provides a connection to IS-1 compatible pulse generators.

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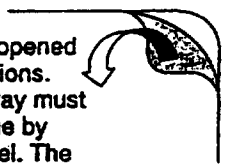
IMPLANT INFORMATION

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

Items packaged with the SWEET TIP Rx leads include the following:

- Soft straight and J-shaped stylets (0.014-in diameter [0.36-mm], green knobs)
- Firm straight and J-shaped stylets (0.016-in diameter [0.41-mm], white knobs)
- Stylet guide
- Vein pick
- Literature

Opening Instructions



The outer package and sterile tray may be opened by authorized personnel under clean conditions. To ensure sterility, the sealed inner sterile tray must be opened using accepted aseptic technique by scrubbed, masked, sterile-gowned personnel. The sterile tray is opened by peeling back the cover.

Sterilization

The lead and accessories are packaged sterile and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant/CPI representative.

Surgical Preparation

Instrumentation for heart monitoring, imaging (fluoroscopy), external defibrillation, and pacing threshold and sensitivity measurements should be available during implantation. Sterile duplicates of all implantable items also should be available for use if accidental damage or contamination occurs. Always isolate the patient from potentially hazardous current leakage when using electrical instrumentation.

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Patient Counseling Information

A Lead Information card accompanies this manual. For additional copies, please contact: Guidant Corporation, Cardiac Rhythm Management, 4100 Hamline Avenue North, St. Paul, MN 55112-5798. Telephone: (651) 582-4000.

See the enclosed Lead Information card for more information.

Accessory Options

Pacemaker Accessory Kit

Guidant/CPI has an operating room pacemaker accessory kit available that contains many of the tools, accessories, and adapters commonly used for lead implantation, repositioning, or both. Contact the nearest Guidant/CPI representative to order these accessories.

Suture Sleeve

The suture sleeve is an adjustable, tubular reinforcement positioned over the outer lead insulation. It is designed to secure and protect the lead at the venous entry site after distal electrode fixation. Use of the suture sleeve helps to optimize device longevity and reduces the possibility of structural damage caused by suturing directly over the lead body.

If a suture sleeve supplied on the lead becomes damaged, a lead anchor should be used in its place. It is available from Guidant/CPI as an accessory item.

The following items are packaged with the lead and are also available from Guidant/CPI as accessory items:

Stylets

A stylet inserted in the lead aids in positioning the lead tip in the heart. Stylets are packaged with the SWEET TIP Rx lead, providing firm and soft options for straight and J-shaped stylets (Figure 1): firm stylets have white knobs and soft stylets have green knobs. A soft straight stylet is preinserted in the packaged lead.

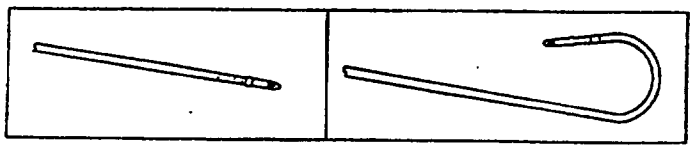

Figure 1. Lead with straight stylet inserted. Lead with J-shaped stylet inserted.

Stylet Guide

A stylet guide is packaged with the lead and is intended to ease insertion of a stylet into the lead (Figure 2).

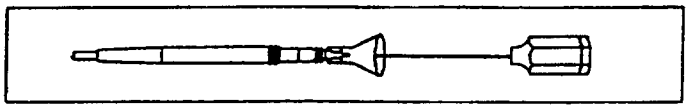

Figure 2. Using the stylet guide.

Vein Pick

The vein pick is a sterile, disposable, nontoxic, nonpyrogenic, plastic device designed to assist the physician during entry of the lead's electrode tip into the vein.

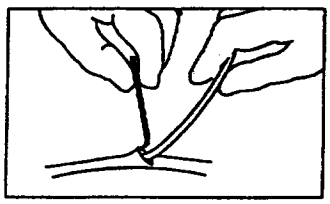

Figure 3. Using the vein pick.

To use the vein pick during a cutdown procedure, isolate and open the selected vein using an appropriate scalpel or scissors. Introduce the point of the vein pick via this incision into the lumen of the vein (Figure 3). With the point of the vein pick facing in the direction of the desired lead passage, gently raise and tilt the pick. Pass the lead under the vein pick and into the vein.

CAUTION: The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure. Be sure that the vein pick does not puncture the silicone rubber insulation of the lead. This might allow body fluids to seep into the lead and could prevent proper lead function.

Handling the Lead

Observe the following cautions when handling SWEET TIP Rx leads:

CAUTIONS:

- Do not wet the mannitol capsule at the tip of the lead before implantation. This will cause the capsule to begin to dissolve and will shorten the time during which the helix is protected. This may also begin elution of the steroid and may reduce the amount of steroid available when the lead is implanted.
- Always protect the lead conductor insulation from surface contamination .
- Do not allow the electrode surfaces to come in contact with surface contaminants.

- To prevent damage to the lead or potential lead dislodgment, do not use excessive force or surgical instruments in handling. Use a suture sleeve to avoid placing the lead under extreme tension.
- Avoid bending the coil conductor; this may weaken the structure. Although pliable, a lead is designed to tolerate only normal flexing and tension.
- Do not apply pressure to the protective capsule over the electrode tip. If the capsule is damaged, the dissolving time may be shortened and/or the helix may be bent. If the helix is bent, the torsional fracture resistance of the helix may be reduced.
- Do not alter the electrodes or use a lead with a deformed helix. **Do not attempt to straighten or realign the fixation helix.**
- Mineral oil should never come in contact with a Guidant/CPI porous-tipped lead electrode. Mineral oil on the porous tip may inhibit tissue ingrowth and conduction.

Implantation

Inserting the Stylet

Choose a stylet according to the firmness desired. Remove the preinserted stylet before inserting a different one.

Gently curve the preferred stylet with any sterile, smooth-surfaced instrument (eg, 10- or 12-cc syringe barrel) (Figure 4) and carefully insert the stylet through the lumen of the conductor. A sharp bend in the stylet may straighten as it passes through the lumen of the terminal pin. A gentle curve is less likely to straighten.

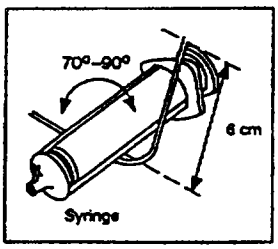

Figure 4. Curve the stylet.

CAUTION: Do not bend the lead with the stylet in place. Bending the lead may damage the conductor and insulation material.

NOTE: *To optimize stylet insertion into the lead, do not allow body fluids to come in contact with the stylet.*

Inserting the Lead

The lead may be inserted using one of the following methods:

- Via cutdown through the left or right cephalic vein.

  Only one incision (below the clavicle) is required to insert the lead through the cephalic vein. The endocardial lead is inserted into the right or left cephalic vein in the deltopectoral groove.

  The vein pick packaged with this lead may be used during a cutdown procedure to aid insertion of the lead into the vein. Before inserting the lead see "Accessory Options" for instructions on using the vein pick. Use of a 9 Fr introducer for cephalic vein lead induction may help minimize venous tissue trauma near the lead insertion site.

- Percutaneously or via cutdown through the subclavian vein or internal jugular vein—typically the left subclavian or right internal jugular vein.

CAUTION: When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle to avoid clavicle/first rib damage to the lead. Lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament.[1] Excessive lead compression has also been reported in patients with anatomical abnormalities between the clavicle and first rib.[2]

Leads placed by percutaneous subclavian venipuncture should enter the subclavian vein where it passes over the first rib (rather than more medially) to avoid entrapment by the subclavius muscle or ligamentous structures associated with the narrow costoclavicular region.[3] Guidant/CPI suggests introducing the lead into the subclavian vein near the lateral border of the first rib.

The syringe should be positioned directly above and parallel to the axillary vein to reduce the chance that the needle will contact the axillary or subclavian arteries or the brachial plexus. Use of fluoroscopy is helpful in locating the first rib and in guiding the needle. The steps below explain how to identify the skin entry point and define the course of the needle toward the subclavian vein where it crosses the first rib.

1. Referring to Figure 5, identify points St (sternal angle) and Cp (coracoid process).

2. Visually draw a line between St and Cp, and divide the segment into thirds. The needle should pierce the skin at the junction of the middle and lateral thirds, directly above the axillary vein (point Ax).

3. Place an index finger on the clavicle at the junction of the medial and middle thirds (point V), beneath which point the subclavian vein should be located.

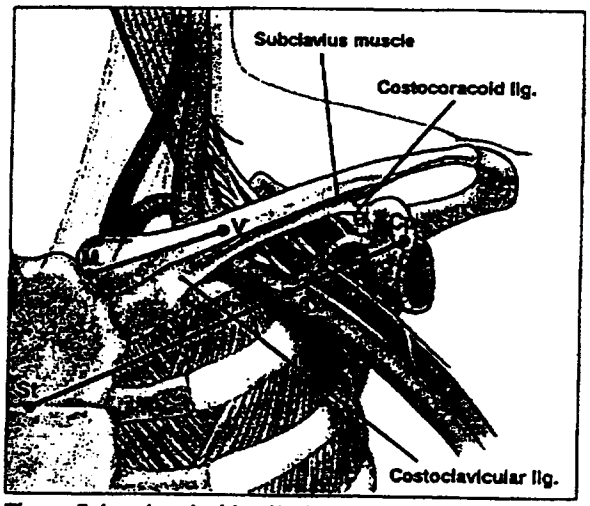

Figure 5. Landmarks identify the entry point for a percutaneous subclavian venipuncture.

4. Press a thumb against the index finger and project one or two centimeters below the clavicle to shield the subclavius muscle from the needle (when hypertrophy of the pectoralis muscle is apparent, the thumb should project about two centimeters below the clavicle because the subclavius muscle could be hypertrophied as well) (Figure 5).

5. Feel with the thumb the pressure from the passage of the needle through the superficial fascia; direct the needle deep into the tissues toward the subclavian vein and the underlying first rib. Fluoroscopic guidance will reduce the chance that the needle would pass below the first rib and into the lung.

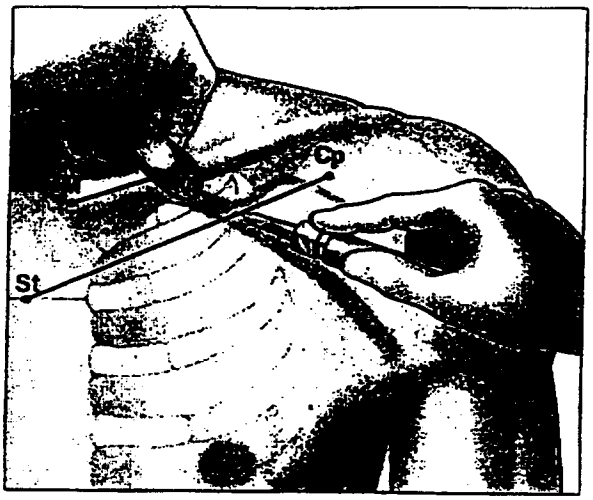

Figure 6. Location of thumb and needle entry.

CAUTION: When implanting the lead via a subclavian puncture, allow slack in the lead between the distal suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region.

Handling the Fixation Helix

As soon as the capsule is inserted into the vein, the capsule begins to dissolve. The fixation helix remains encapsulated for approximately five minutes.

If more than five minutes have elapsed since the introduction of the lead, the protective capsule may be completely dissolved. The following points must be carefully observed to avoid possible tissue snagging when inserting a lead having an exposed fixed helical coil:

CAUTIONS:

- **The method used to direct positive fixation leads through the veins to the heart is different from that used with other leads. To prevent entanglement, use the stylet to steer while rotating the lead body continuously counterclockwise. Use of the lead body for steering may result in tissue snagging and damaging the fixation helix.**
- Continuous *counterclockwise* rotation of the lead during maneuvering is necessary to avoid inadvertent tissue trauma.

- Do not rotate the lead *clockwise* until correct position has been achieved and fixation is intended.
- Should dislodgment occur, immediate medical care is required to resolve the electrode position.

Advance the lead promptly to the appropriate heart chamber while directing the electrode with the appropriate stylet and rotating the lead body counterclockwise. Counterclockwise lead rotation helps to prevent accidental fixation and releases the electrode helix after fixation has occurred.

Positioning the Lead

After immersion in blood, the SWEET TIP Rx electrode is electrically conductive to allow mapping of potential electrode positions. Mapping of the atrium or ventricle prior to lead fixation is recommended as it can reduce the potential need for multiple lead positionings.

Atrial Position. With the straight stylet in the lead, advance the lead transvenously into the right atrium while guiding the electrode with the stylet. By replacing the straight stylet with a J-shaped stylet, the lead electrode can be directed upward into the atrial appendage (Figure 7).

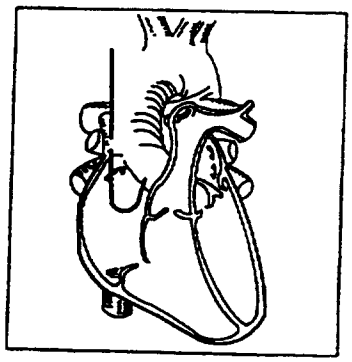

Figure 7. Atrial placement.

NOTES:

- *When possible, the tip electrode should be positioned perpendicular to the heart wall prior to fixation. This will help reduce stress on the helix as the lead is affixed to the heart wall.*
- *When the distal electrode is positioned correctly, lead movement is from side-to-side during each atrial contraction (anteroposterior view). In the absence of spontaneous atrial contraction, pace the atrium through the lead and check tip movement.*

Ventricular Position. With the gently curved stylet in the lead, advance the lead transvenously into the apex of the right ventricle where it can be affixed in the endocardium. If necessary, remove the curved stylet and use a straight stylet to advance the tip deeper into the trabeculae. Before affixing the distal electrode helix, use a fluoroscope to ensure that the lead is in the ventricle and not in the coronary sinus (Figure 8).

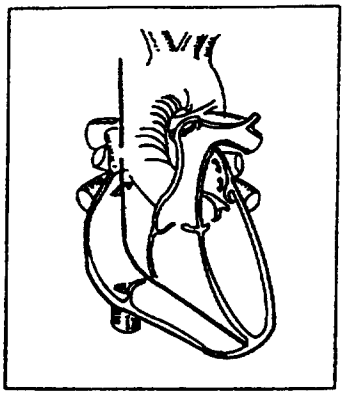

Figure 8. Ventricular placement.

Lead Fixation

When the correct position has been achieved and five or more minutes have passed allowing the capsule to dissolve completely, affix the distal electrode helix into the heart wall.

NOTE: The stylet must be fully inserted during fixation or repositioning.

If implanting a **unipolar** SWEET TIP Rx lead (Models 4143, 4144, 4145), affix the electrode helix into the heart wall by rotating the lead clockwise approximately 6 turns or until torsional resistance is felt.

If implanting a **bipolar** SWEET TIP Rx lead (Models 4243, 4244, 4245), affix the electrode helix into the heart wall by rotating the lead clockwise approximately 3–5 turns, or until torsional resistance is felt.

CAUTIONS:

- If the stylet begins to turn while fixating the lead, hold the stylet stationary while rotating the lead. Rotating the stylet during electrode fixation dislodges the electrode helix.
- Do not rotate the lead clockwise more than 10 turns when affixing the electrode helix to the heart wall. Excessive rotation may cause helix breakage.

After fixation, allow the lead to counterrotate passively, approximately 1.5 turns, to release excess torsional stress. Failure to observe counterrotation indicates incomplete fixation. Repeat clockwise rotations using the procedures previously discussed until torsional resistance is felt and counterrotation is observed upon release. Check the stability of the electrode by having the patient cough or take a deep breath.

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For atrial implantation, after the lead tip is affixed to the heart wall, check for proper lead movement as follows: As the patient exhales, the lead's J shape should appear secure in the atrial appendage. As the patient inhales, the lead's J shape straightens (forms an L shape).

Repositioning the Lead

If the lead needs repositioning, verify the stylet is in the lead and rotate the lead counterclockwise several turns to release the fixation helix. Fluoroscopy is recommended to verify the helix is disengaged completely from the heart wall before attempting to reposition the lead. Reaffix the electrode using the handling and positioning procedures previously discussed.

CAUTIONS:

- Do not alter the electrodes or use a lead with a deformed helix. Do not attempt to straighten or realign the fixation helix.
- Chronic repositioning may adversely affect the lead's low-threshold performance because the steroid may be depleted.

After the distal electrode is in the proper position, withdraw the stylet 8 to 10 cm and verify the electrical performance of the lead.

Electrical Performance

Evaluate lead placement by determining P- or R-wave amplitude and pacing threshold. Verify the electrical performance of the lead *before* attaching the lead to the pulse generator and *after* allowing sufficient time for the effect of local tissue trauma to subside (approximately 10 minutes). Threshold and sensing data may be measured directly from the lead using a pacing system analyzer.

For bipolar leads the lead connector pin is the cathode (–) conductor and should be connected to the negative conductor of the pacing system analyzer's patient cable. The ring of the lead connector is the anode (+) conductor and should be connected to the positive conductor of the patient cable. TIP TO TIP and RING TO RING describes the lead conductor to lead electrode connections.

Sensing signals also may be measured with an ECG recorder or oscilloscope. Electrical performance should fall within the recommended values listed in Table 8.

For atrial implantation, after the lead tip is affixed to the heart wall, check for proper lead movement as follows: As the patient exhales, the lead's J shape should appear secure in the atrial appendage. As the patient inhales, the lead's J shape straightens (forms an L shape).

Repositioning the Lead

If the lead needs repositioning, verify the stylet is in the lead and rotate the lead counterclockwise several turns to release the fixation helix. Fluoroscopy is recommended to verify the helix is disengaged completely from the heart wall before attempting to reposition the lead. Reaffix the electrode using the handling and positioning procedures previously discussed.

CAUTIONS:

- Do not alter the electrodes or use a lead with a deformed helix. Do not attempt to straighten or realign the fixation helix.
- Chronic repositioning may adversely affect the lead's low-threshold performance because the steroid may be depleted.

After the distal electrode is in the proper position, withdraw the stylet 8 to 10 cm and verify the electrical performance of the lead.

Electrical Performance

Evaluate lead placement by determining P- or R-wave amplitude and pacing threshold. Verify the electrical performance of the lead *before* attaching the lead to the pulse generator and *after* allowing sufficient time for the effect of local tissue trauma to subside (approximately 10 minutes). Threshold and sensing data may be measured directly from the lead using a pacing system analyzer.

For bipolar leads the lead connector pin is the cathode (–) conductor and should be connected to the negative conductor of the pacing system analyzer's patient cable. The ring of the lead connector is the anode (+) conductor and should be connected to the positive conductor of the patient cable. TIP TO TIP and RING TO RING describes the lead conductor to lead electrode connections.

Sensing signals also may be measured with an ECG recorder or oscilloscope. Electrical performance should fall within the recommended values listed in Table 8.

Table 8. Recommended threshold and sensing measurements[1]

Atrial Data	Ventricular Data
Voltage threshold[2] ≤ 1.0 V	Voltage threshold[2] ≤ 1.0 V
Current threshold[2] ≤ 1.5 mA	Current threshold[2] ≤ 1.5 mA
P-wave amplitude ≥ 2.0 mV	R-wave amplitude ≥ 5.0 mV

1. Measured approximately 10 minutes after fixation.
2. Pulse width setting at 0.5 ms.

If the measurements do not conform to these values, reposition and then reaffix the electrode using the positioning procedures previously discussed. Verify that measurements fall within the recommended values.

NOTE: Low stimulation threshold readings indicate a desirable safety margin, since stimulation threshold may rise after implantation.

Securing the Lead

After the electrodes are satisfactorily positioned, secure the lead to the vein to achieve permanent hemostasis and lead stabilization. Suture sleeves are provided for this purpose.

Venous Cut-Down Technique

Slide the suture sleeve into the vein and ligate the vein around the suture sleeve to obtain hemostasis (Figure 9). Secure a suture around the suture sleeve, then suture the sleeve to adjacent fascia to prevent lead movement. Tying the suture around the suture sleeve prior to suturing to tissue reduces the risk of tissue necrosis caused by a tight suture and thus increases the security of the ligature. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

NOTE: If venous entry is made using a Guidant/CPI lead introducer, ligate the lead to the adjacent fascia using the suture sleeve to prevent lead movement.

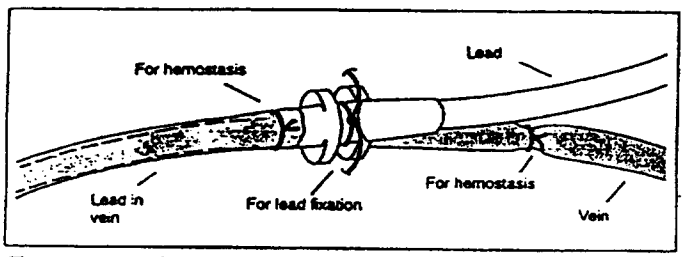

Figure 9. Securing lead with suture sleeve.

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Percutaneous Implant Technique

Peel back the introducer sheath and slide the suture sleeve deep into the tissue. Refer to the Venous Cut-Down Technique section for information on securing the suture sleeve.

CAUTIONS:

- Do not kink, twist, or braid the lead terminal with other leads as doing so could cause lead insulation abrasion damage.
- When ligating the vein, avoid too tight a stricture. A tight stricture might damage the silicone rubber insulation or sever the vein. Avoid dislodging the electrode tip during the anchoring procedure.
- Do not remove or cut the suture sleeve from the lead as it may cause lead damage.

Connection to a Pulse Generator

When the lead is secured at the venous entry site, reverify threshold measurements and connect the lead to the pulse generator using the procedure described in the applicable pulse generator physician's manual.

CAUTIONS:

- **Insert the IS-1 lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation damage near the terminal ring that could result in lead damage.**
- Remove the stylet and the stylet guide before connecting the lead to the pulse generator. Under no circumstances should the stylet be left in the lead. Leaving the stylet in the lead could cause (1) lead perforation, (2) myocardial perforation, or (3) inability to remove the stylet and reposition the lead.

NOTES:

- *If necessary, lubricate the lead terminal sparingly with sterile water to make insertion easier.*
- *If the lead terminal pin will not be connected to a pulse generator at the time of lead implantation, the lead connector must be capped before closing the pocket incision. Place a suture around the lead cap to keep it in place.*

Gently coil the excess lead wires and place them in a separate pocket above or to the side of (not behind) the pulse generator, giving consideration to lead tension and device motion. It is im-

portant to place the lead into the pocket in a manner that minimizes pressure and reduces lead-on-lead and/or lead-on-pulse generator contact.

Explantation

Return all leads to Guidant/CPI. Examination of explanted leads may provide information for continued improvement in system reliability. Use a Guidant/CPI Returned Product Kit to properly package the lead and complete an Observation/Complication/Out-of-Service Report form. Send the form and kit to Guidant/CPI at the address on the back of this manual.

NOTE: Disposal of explanted devices is subject to local, state, and federal regulations. Contact your Guidant/CPI representative or call Guidant/CPI at 1-800-CARDIAC or 612-638-4000 for a Returned Product Kit.

REFERENCES

1. Magney JE, et al. Anatomical mechanisms explaining damage to pacemaker leads, defibrillator leads, and failure of central venous catheters adjacent to the sternoclavicular joint. *PACE*. 1993;16:445–457.
2. Suzuki Y, Fujimori S, Sakai M, et al. A case of pacemaker lead fracture associated with thoracic outlet syndrome. *PACE*. 1988;11:326–330.
3. Magney JE, et al. A new approach to percutaneous subclavian venipuncture to avoid lead fracture or central venous catheter occlusion. *PACE*. 1993;16:2133–2142.

SPECIFICATIONS (Nominal)

Model	4143, 4144, 4145 Unipolar	4243, 4244, 4245 Bipolar
Length	4143 – 45 cm 4144 – 52 cm 4145 – 59 cm	4243 – 45 cm 4244 – 52 cm 4245 – 59 cm
Compatibility	Guidant/CPI pulse generators that accept 3.2-mm IS-1 connectors	Guidant/CPI pulse generators that accept 3.2-mm IS-1 connectors
Recommended lead introducer	9 Fr	9 Fr
Diameter:		
Lead body	2.2 mm	2.2 mm
Distal electrode	2 mm	2 mm
Proximal electrode	NA	2.6 mm
Fixation helix	1.3 mm	1.3 mm
Active surface area:		
Distal electrode	11 mm^2	11 mm^2
Proximal electrode	NA	35 mm^2
Distance between electrodes	NA	11 mm
Steroid	1.0 mg dexamethasone acetate	1.0 mg dexamethasone acetate
Fixation helix penetration depth	1.5 mm	1.5 mm
Number of coils in fixation helix	1.5 turns	1.5 turns
Conductors	Double-wound helical coil	Double- and quad-wound helical coils
Material:		
Electrode	Platinum iridium	Platinum iridium
Conductor	MP35N nickel	MP35N nickel
Insulation	Silicone rubber	Silicone rubber
Capsule	Mannitol	Mannitol

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LEAD INFORMATION

Warranty Disclaimer

Guidant/CPI cannot warrant or guarantee its leads.

Since leads are vulnerable to damage from improper handling and since they must function in a hostile environment, Guidant/CPI leads may fail to perform for a variety of reasons. Guidant/CPI exercises care in the design, materials used, manufacturing, and testing of Guidant/CPI leads. However, due to the stringent conditions under which leads must function, Guidant/CPI leads are sold "as is" without any warranty. Guidant/CPI may, at its discretion, replace damaged leads returned to Guidant/CPI. All leads returned to Guidant/CPI become the property of Guidant/CPI.

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